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REMARKS/ARGUMENTS

Claims 28, 29, 33, and 36-40 are pending in the application and have been rejected.

Applicants note their previous amendments overcame the rejection of claims 28, 29, 33 and 36 under 35 USC 112, second paragraph.

Applicants further note the terminal disclaimer filed previously has been accepted and recorded, rendering moot the double patenting rejection of claims 33 and 36.

Rejection under 35 USC §112

Claims 33, 28, 29 and 36 were rejected under 35 USC 112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which Applicant regards as the invention.

In particular, the Examiner avers that claims 37 and 40 are indefinite over the recitation of "from 90 to 400 nucleotides as measured or 3' to 3' . . .". Applicants have corrected this typographical error and removed the word "or" in both cases. Applicants respectfully request this rejection be withdrawn.

Rejection under 35 U.S.C. §102

Claims 28, 33, 36, 37, 38 and 40 were rejected under 35 USC §102(b) as being anticipated by Frank et al. as evidenced by the Promega catalog (page 67, 1993-93).

It is averred that Frank et al. teach simultaneous amplification and subsequent simultaneous detection of three different target nucleic acids using three different primer pairs; the target nucleic acid are CMV MIE gene, CMV LA gene and human beta-hemoglobin gene; that primers used for amplification of these sequences are listed in Table 1; a pair of primers CMV MIE (1st round) which are hybridizable to the opposing strands of the CMV LA gene, and a pair of primers, hemoglobin (1st round), which are hybridizable to the opposing strands of the hemoglobin gene, that although Frank et al. do not teach melting temperatures of the primers but the Examiner calculated them as 3.3 degrees C of each other, that Frank et al. teach a PCR reaction which contained 200 uM of each dNTP, 10% of 10x Taq DNA polymerase buffer (from Promega) and 5 units Taq polymerase; that the PCR reaction parameters for the first round included 2 minutes at 64 degrees C for primer annealing and 2 minutes at 72 degrees C for primer extension (page 450 para 3 and 4); the amplification products were simultaneously detected by electrophoresis on a 3% NuSieve/1% agarose gel containing 0.5 ug/mL ethidium bromide. While the Examiner admits that Frank et al. do not explicitly teach Taq DNA polymerase cofactor Mg²⁺ or Mn²⁺, Frank et al. teach using 10X Taq polymerase buffer from Promega, and as evidenced by 1992-93 Promega catalog, 10X polymerase buffer contained MgCl₂.

Applicants traverse this rejection, however, without acquiescing in the rejection, Applicants submit herewith the appended Declaration under 37 CFR 1.131 of coinventor Susan M. Werner (nee Atwood, see appended Declaration for name change of coinventor), the aforementioned Rule 131

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Amdt. dated June 29, 2004

Reply to Office Action of December 29, 2003

Declaration including Exhibits A, B, C and D, evidencing

conception and reduction to practice of the claimed invention prior to July 1992, which date is prior to the effective date of the Frank et al. reference. With submission of this Declaration and its appended Exhibits, withdrawal of the rejection is courteously requested.

Rejection under 35 U.S.C. §103(a)

Claims 29 and 39 were rejected under 35 U.S.C. 103(a) as being unpatentable over Frank et al. and Picone et al. (WO 92/11273).

The Examiner avers Frank et al. teach detection of amplification products on Southern blots with probes complementary to the amplified fragments, but do not teach capture probes on solid support or probes having from 10 to 40 nucleotides and T_m s greater than about 50 degrees C, being hybridizable to a nucleic acid sequence at a temperature in the range of from 40 to 55 degrees C.

The Examiner further avers that, regarding claims 29 and 39, Picone et al. teach amplification products by hybridization, using multiple capture probes immobilized on solid support (page 6, lines 10-19; page 7, lines 11-19) which can detect different species within the same genus of pathogens or more than one genus; that Picone et al. teach probes for the detection of amplified Legionella genes having lengths of 18bp and melting temperatures of 58 and 60 degrees C (page 28, lines 20-24), the hybridization conditions being 20 minutes at 50-55 degrees C (page 32, lines 30-36).

The Examiner avers it would have been prima facie obvious to one of ordinary skill in the art at the time of

the invention to have used the capture probes designed according to Picone et al. in the method of Frank et al.; that the motivation to do so, provided by Picone et al., would have been that multiple specific capture probes would normally be immobilized individually on a solid support and as a result the assay would require the use of more test sample, more time to perform the test and more interpretation by the user (page 6 lines 10-19).

Applicants traverse this rejection, however, without acquiescing in the rejection, Applicants submit herewith the appended Declaration under 37 CFR 1.131 of coinventor Susan M. Werner (nee Atwood, see appended Declaration for name change of coinventor), the aforementioned Rule 131 Declaration including Exhibits A, B, C and D, evidencing conception and reduction to practice of the claimed invention prior to January 20, 1990, which date is prior to the effective date of the Frank et al. reference and the Picone et al. reference. It is specifically pointed out that Exhibit A to the Declaration Under 37 CFR 1.131 provides evidence of conception and reduction to practice of the limitations of claims 29 and 39, that is in particular, use of a capture reagent. See Exhibit A at page 97 stating "SureCell Results." Capture probes to specifically hybridize with the amplicons from each primer set were used (GAG and ENV), along with a control capture probe (LTR) that should not hybridize with either amplicon. Inventors employed the SureCell device (Eastman Kodak Co., U.S.) which employed a water-insoluble support to which was covalently attached a capture probe specific to a nucleic acid sequence. See specification at page 33, line 5-page 36, line 9, and in particular at page 33, line 31 to page 34, line 26.

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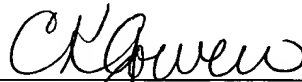
With submission of this Declaration and its appended Exhibits, withdrawal of the rejection is courteously requested.

Entry of these amendments and allowance of the application on the merits is earnestly solicited.

If a telephone interview would be of assistance in advancing prosecution of the subject application, the Examiner is invited to telephone Applicants' undersigned attorney at the number provided.

If any fees are due in connection with the filing of this amendment, authorization is hereby granted to charge the amount of such fee to Deposit Account No.10-0750/CDS-226/CKG in the name of Johnson & Johnson.

Respectfully submitted,



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